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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,596	02/19/2004	Chen W. Liaw	AREN-011CON(11.US12.CON)	5835

65643 7590 03/23/2007

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EXAMINER	
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ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/782,596	**Applicant(s)** LIAW ET AL.	
	Examiner Ruixiang Li	**Art Unit** 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *5-8,21-26 and 28-30*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Ruixiang Li

RUIXIANG LI, PH.D.
PRIMARY EXAMINER

Continuation of 11. does NOT place the application in condition for allowance because: all the pending rejections are maintained.

(i). The rejections of claims 5-8 and 21-26 under 35 U.S.C. § 101 and 35 U.S.C. §112, 1st paragraph

Applicants argue that the claimed method can be used to identify compounds that increase the "well-being" of substantia nigra cells and stave off or slow the progression of Pakinson's disease. This is not persuasive because the instant disclosure has not disclosed that the hARE-2 is linked to Parkinson's disease. Moreover, since the biological function of hARE-2 is not disclosed, the compound identified in the methods using hARE-2 does not have a specific and substantial utility. The use of compounds identified in the method in increasing the "well-being" of substantial nigra cells is a "throw-away" utility.

Applicants argue that the claimed screening methods can be employed to identify compounds that can be employed in the study, diagnosis or monitoring of Parkinson's disease. This is not persuasive because the instant disclosure fails to disclose that an agonist, partial agonist, or inverse agonist of the GPCR of SEQ ID NO: 20 can be used for the diagnosis of Parkinson's disease. In addition, the use of a compound identified by the claimed method in the study of Parkinson's disease is considered a research utility and it does not represent a specific and substantial utility.

Applicants disagrees with the examiner with respect to the use of the claimed method to identify compounds for treating Parkinson's diseasse and other diseases caused by degeneration of the substantia niga. The Examiner's position has been clearly stated in the final rejection (page 4).

(ii). The rejection of claims 28-30 under 112, 1st paragraph, Written Description

Applicants argue that the GPCRs recited in the rejected claims are naturally produced and encoded by a polynucleotide that hybridizes to SEQ ID NO: 19. Applicants argue that given this, one of skill in the art would not expect the incredibly broad range of variation the Examiner seems to read into the claims.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, the claims do not require that the polypeptides recited in the claims possess any particular biological activity, nor any particular conserved structure, nor other disclosed distinguishing feature. Secondly, the claims recite "stringent conditions", however, only the washing conditions are given, which would yield structurally and functionally unrelated polypeptides. Furthermore, the mere disclosure of SEQ ID NO: 20 is not sufficient to support the genus of recited in the claims. Finally, the specification fails to describe the features of the endogenous version of the polypeptide of SEQ ID NO: 20 so as to one of skill in the art can readily recognize it.

Applicants also argue that one of skill in the art would not expect substantial structural variation among species encompassed within the scope of the claims. This is not persuasive because the issue here is whether Applicants were in possession of the claimed invetion at the time the instant case was filed. it is not the case here.

(iii). The rejection of claims 5-8, 21-26, and 28-30 under 35 U.S.C. 112, second paragraph

Applicants argue thtat given the discussion in the Background section of this patent application, one of skill in the art sould readily understand the phrase " measure the ability of the compound or compounds that inhibit or stimulate said receptor" means measuring coupling to a G protein or a signal that is transduced by the receptor. This is not persuasive because the claims are required to particularly point out and distinctly claim the subject matter which applicant regards as the invention under 35 U.S.C. 112, second paragraph.

Applicants argue that the terms "agonist", "partial agonist", and "inverse agonist" are art recognized terms with well defined meaning, one of skill in the art would have no trouble understandering how they can be detemined. This is not persuasive because the steps of the methods do not necessarily achieve the goal set forth in the claim preamble. The amended claims recite "(c) identifying the compound or compounds that inhibit or stimulate said receptor as an agonist, partial agonist, or inverse agonist of said receptor". However, it is unclear how an agonist, partial agonist, or inverse agonist of said receptor is determined and correlated to the preamble.

Applicants refers to the page 5 of the instant application for the term "endogenous" and argue that one of skill in the art would recognize that the endogenous receptors recited in the rejected claims are receptors that are naturally produced. This is not found to be persuasive because the instant specification fails to describe the features of "an endogenous version" of the polypeptide of SEQ ID NO: 20 so as to one of skill in the art can readily recognize it.

Applicants argue that the meaning of "stringent conditions" would be well known in the art. This is not persuasive because only the washing conditions are given, leaving the hybridization conditions undefined. Since neither the specification nor the prior art defines the term unambiguously, the claims are indefinite.

(iv). The objection to claims 5, 7, 21, 24, and 28 for minor informaliy is withdrawn in view of amended claims.

RUIXIANG LI, PH.D.
PRIMARY EXAMINER